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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,290	02/07/2006	Thor Las Holtet	08-349-WO-US	6045

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

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01/25/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/533,290	Applicant(s) HOLTET ET AL.	
	Examiner Prema M. Mertz	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 19, 20, 22, 23, 30 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 19, 20, 22, 23, 30 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/10/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/10/10 has been entered.

2. Claims 2-18, 21, 24-29, and 31-34, have been cancelled previously.

Previously presented claims 1, 19-20, 22-23, 30 and 35 are pending and under consideration by the Examiner.

3. Receipt of applicant's arguments and amendments filed on 8/10/2010 is acknowledged.

4. Applicant's arguments filed on 8/10/10 have been fully considered but were non-persuasive. The issue remaining and new issue are stated below.

Claim rejections-Double Patenting

Non-statutory double patenting rejection (obviousness-type)

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5a. Claims 1, 19-20, 22-23, 30, and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent 7,642,044 ('044). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 19-20, 22-23, 30, 35 of U.S. Patent '044 (having one common inventor with the instant application), claims a trimeric polypeptide complex comprising three monomer polypeptides, wherein (i) each of said monomer polypeptides comprises a tetranectin trimerising structural element (TTSE), said TTSE being a polypeptide having at least 68% amino acid sequence identity with the consensus sequence shown in SEQ ID NO:40 and (ii) at least one of said monomer polypeptides is covalently linked to at least one heterologous moiety, where said at least one heterologous moiety is different from any of the fusion proteins CIIH6FXTN123, H6FXTN123, H6FXTN12, H6FCTN23, the sequences of which are shown in SEQ ID NOs:24-27, and said complex remains as a trimer at a temperature of at least 60°C. Claim 17 of U.S. Patent '044 further recites that the at least one heterologous

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moiety is selected from the group consisting of:

- (a) a ligand binding structure;
- (b) a toxin;
- (c) a detectable moiety;
- (d) an in situ activatable substance;
- (e) an enzyme;
- (f) a radioactive moiety;
- (g) a cytokine;
- (h) a non-proteinaceous polymer;
- (i) a polyalcohol;
- (j) a polysaccharide;
- (k) a lipid;
- (l) a polyamine;
- (m) a photo cross-linking agent; and
- (n) a group facilitating conjugation of the polypeptide to a target, wherein the conjugation encompasses both covalent and non-covalent linkages.

This rejection is maintained for reasons of record set forth at pages 9-11 of the previous Office action (8/22/2008), pages 14-16 of the previous Office action (2/12/2009), pages 10-12 of the previous Office action (7/24/09) and pages 2-4 of the previous Office action (3/9/2010).

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Applicants argue that they disagree with the Action's assertion that in view of the '434 Patent, the trimeric polypeptides of the instant application would have been obvious to one of ordinary skill in the art at the time the instant invention was made. Furthermore, Applicants contend that because bivalent antagonists of the TNF superfamily were well known at the time the instant application was filed, it would not have been obvious to one of ordinary skill in the art to make the claimed trimeric polypeptides comprising a TNF receptor and tetranectin trimerising structural element (TTSE), at the time the instant application was filed, two TNF antagonists - infliximab and etanercept - were approved for the treatment of arthritis. Scallon et al., J Pharmacol Exp Ther.301 (2): 418-26, 418 (2002), and that these molecules fundamentally differ with regard to their molecular structures, binding specificities, and manner in which they neutralize TNF. Id. However, contrary to Applicants arguments, Applicants are misconstruing the rejection by the Examiner. Instant claims 1, 19-20, 22-23, 30, and 35 which claim a trimeric polypeptide comprising three monomers, wherein each monomer comprises a cytokine binding member domain and a tetranectin trimerising domain, are species claims to claims 1, 19-20, 22-23, 30, and 35 of U.S. Patent '044 because the claims in the instant application are of narrower scope than the claims in the '044 U.S. Patent. However, the claims in the instant application are obvious from the patented claims because the claims in the instant application are directed to specific embodiments encompassed by claims 1-60 of U.S. Patent '044. The product of the claims in the instant application is included in claims 1, 19-20, 22-23, 30, and 35 of U.S. Patent '044. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a trimeric polypeptide recited in the claims of U.S. Patent '044 included the trimeric polypeptide of the instant application and encompassed the species claims

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in the instant application. The claims of U.S. Patent '044 if infringed upon would also result in infringement of the species claims of the instant application.

In addition, the Court in KSR held that "Neither §103's enactment nor Graham's analysis disturbed the Court's earlier instructions concerning the need for caution in granting a patent based on the combination of elements found in the prior art." KSR v. Teleflex, 550 U.S., 82 USPQ2d 1385, 1389 (2007). The KSR court stated that "a combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." KSR at 1389.

Furthermore, the KSR court concluded that "obvious to try" may be an appropriate test under 103. The Supreme Court stated in KSR:

When there is motivation "to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." KSR Int'l Co. v. Teleflex Inc., 127 S.Ct. 1727, 82 USPQ2d 1385, 1397 (2007).

Therefore, it would have been obvious to one having ordinary skill in the art that a trimeric polypeptide as recited in the '044 patent encompassed the trimeric polypeptide of the instant claims since the claims are of overlapping scope.

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5b. Claims 1, 19-20, 22-23, 30, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 56-86 of copending Application 12/405,021 ('021). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 56-86 of copending Application '021 (having one common inventor with the instant application), claims a trimeric polypeptide complex comprising three monomer polypeptides, wherein (i) each of said monomer polypeptides comprises a) a first functional amino acid sequence that is capable of forming a trimeric complex with two other first functional amino acid sequences and that has up to five amino acid substitutions at positions 10, 17, 20, 21, 24, 25, 26, 28, 29, 30, 31, 32, 33, 34, or 35 of the amino acid sequence of SEQ ID NO: 40; and (b) a second functional amino acid sequence that is heterologous to the first functional amino acid sequence; wherein the isolated polypeptide does not consist of the amino acid sequence of SEQ ID NO: 27. Claim 65 of U.S. Application '021 further recites that the second functional amino acid sequence comprises an amino acid sequence encoding all or a part of:

- (a) a ligand binding structure;
- (b) a ligand;
- (c) a receptor binding structure;
- (d) a receptor;
- (e) a detectable moiety;
- (f) an in situ activatable substance;
- (g) an enzyme; or
- (h) a cytokine.

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Instant claims 1, 19-20, 22-23, 30, and 35 claim a trimeric polypeptide comprising three monomers, wherein each monomer comprises a cytokine binding member domain and a tetranectin trimerising domain, are a species of claims 56-86 in the '021 application and encompass subject matter to which the claims in the '021 application are a genus because the claims in the '021 application are of broader scope than the claims in the instant application. However, the claims in the instant application are obvious from the claims in the '021 application because the claims in the instant application are directed to specific embodiments encompassed by claims 56-86. The product in the instant claims is included in claims 56-86 of application '021. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that a trimeric polypeptide recited in instant claims was included in the trimeric polypeptide of the '021 application and encompassed the genus claims in the '021 application, since the claims are of overlapping scope. The claims of the instant application if infringed upon would also result in infringement of the broad claims of the '021 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Claims 1, 19-20, 22-23, 30 and 35 are rejected.

Advisory Information

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Prema Mertz/
Prema Mertz, Ph.D., J.D.
Primary Examiner
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